K123338

MAR 2 8 2013

6. 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Blockade Medical
DATE PREPARED:	March 19, 2013
CONTACT PERSON:	Rebecca K Pine Blockade Medical 18 Technology Dr. Suite 169 Irvine, CA 92618 Phone: (760) 809.5178
TRADE NAME:	Barricade Embolization Coil System
COMMON NAME:	Neurovascular embolization device
CLASSIFICATION NAME:	Neurovascular embolization device
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 882.5950
PRODUCT CODE	HCG
PREDICATE DEVICES:	Guglielmi Detachable Coils- GDC 360° (K103355, K093142) Hydrocoil Embolic System (K120908) Microplex Coil System (K093358)

Substantially Equivalent To:
The Barricade Embolization Coil System is substantially equivalent in intended use, principal of operation and technological characteristics to the Guglielmi Detachable Coils (K103355) the Microplex Coil System (K093358) and the Hydrocoil Embolic System (K120908).

Description of the Device Subject to Premarket Notification:
The Barricade Embolization Coil System (BCS) is a series specialized coils that are inserted into the vasculature under angiographic visualization to embolize intracranial aneurysms and other vascular anomalies. The system consists of an embolization coil implant comprised of platinum/tungsten, affixed to a delivery pusher with an introducer sheath to facilitate insertion into the hub of a microcatheter. The system is available in various shapes, lengths and sizes. The devices are to be placed into aneurysms to create blood stasis, reducing flow into the aneurysm and thrombosing the aneurysm. Upon

positioning coils into the aneurysm, the coils are electrolytically detached from the delivery pusher in serial manner until the aneurysm is occluded.

Indication for Use:
The Barricade Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Barricade Coil System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

Technical Characteristics:
The Barricade Embolization Coil System has similar physical and technical characteristics to the predicate devices as outlined in the table below:

	Barricade Embolization Coil System	**GDC 360° (K103355, K093142)**	**Hydrocoil Embolic System (K120908)**	**Microplex Coil System (K093358)**
	Facilitates endovascular embolization of intracranial aneurysms and other vascular abnormalities	SAME	SAME	SAME
Primary Coil Diameter	0.010"-0.014"	0.010"-0.015"	0.008"-0.015"	0.0095"-0.015"
Coil Secondary diameter	1.5mm – 15mm	1.5mm – 25mm	2mm-24mm	2-24mm
Coil Wire Diameter	0.00125"-0.003"	Unknown	0.002"-0.004"	0.00125"-0.004"
Secondary Shapes	Complex/Helical	Complex/Helical	Helical	Complex/Helical
Coil Types	Framing, Filling, Finishing	Framing, Filling, Finishing	Framing, Filling, Finishing	Framing, Filling, Finishing
Coil length	1cm – 40cm	1cm – 50cm	2cm-50cm	2-68cm
Main Coil Material	Platinum/Tungsten alloy	Platinum/Tungsten alloy	Platinum/Tungsten alloy	Platinum/Tungsten alloy
Coil delivery	Stainless steel wire/pusher	Stainless steel wire/pusher	Stainless steel wire/pusher	Stainless steel wire/pusher
Coil detachment	Electrolytic	Electrolytic	Thermo-mechanical	Thermo-mechanical
Detachment equipment	Detachment Control Power Supply, ED2-BL	Boston Scientific Detachable Coil Power Supply or InZone Detachment System	V-Grip Detachment Controller	V-Grip Detachment Controller
Method of supply (coil/delivery system)	Sterile, single use	Sterile, single use	Sterile, single use	Sterile, single use

Performance Data:
All necessary verification and validation testing has been performed for the Barricade Embolization Coil System to assure substantial equivalence to the predicate devices and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Comparative simulated use testing demonstrated that the Barricade Embolization Coil System is substantially equivalent to the predicate devices. Testing included:

- Visual inspection
- Dimensional measurement
- Simulated Use
  - Introduction
  - Tracking
  - Reposition/deployment
  - Detachment
  - Overall Performance
- Detachment Zone tensile
- Stretch Resistance tensile
- Corrosion resistance
- MR compatibility

Biocompatibility and animal testing was performed as follows:

Test	Results	Conclusions
Cytotoxicity Testing - Neutral Red Uptake (NRU)/MEM (implant)	97% cell viability	Non-cytotoxic
Sensitization Testing - Kligman Maximization (implant)	No reaction	Non-sensitizing
Intracutaneous Reactivity (implant)	No significant greater biological reaction than the controls	Non-irritant
Hemolysis (implant)	< 2% hemolysis	Non-hemolytic
Prothrombin Time (implant)	Normal range (10-14sec)	No adverse effect on prothrombin coagulation time
Complement Activation (implant)	No increase observed compared to controls	Does not induce complement activation.
Acute Systemic Toxicity (implant)	Did not induce a significantly greater reaction than controls	Non-toxic
Materials Mediated Pyrogen (implant)	No individual temperature increase of $\geq$ 0.5°C	Non-pyrogenic
Ames Assay (implant)	No significant increase in the number of revertant colonies compared to controls	Not considered mutagenic
Mouse Lymphoma (implant)	No significant increase in mutant frequency	Non-mutagenic
Micronucleus Assay	No statistical increase in	Non-mutagenic (non-genotoxic,

Test	Results	Conclusions
w/confirmation (implant)	micronucleated erythrocytes compared to controls	non-clastogenic)
Implantation, intramuscular (implant)	Bioreactivity rating 3.6	Non-reactive
Systemic Toxicity, 90 day (implant)	The test article did not appear to demonstrate local or systemic signs of toxicity	Non-toxic
Cytotoxicity- MEM Elution (delivery system)	< Grade 2	Non-cytotoxic
Sensitization- Murine Local Lymph Node Assay (delivery system)	Stimulation Indices calculated < 3.0.	Not considered to be sensitizing
ISO Intracutaneous Study (delivery system)	Mean score difference from control $\leq$ 1.0.	Non irritant
ISO Systemic Toxicity Study (delivery system)	No mortality or systemic toxicity observed.	Non-toxic
Hemolysis (delivery system)	Mean hemolytic index was 0%	Non-hemolytic
Materials Mediated Pyrogen (delivery system)	No individual temperature increase of $\geq$ 0.5°C	Non-pyrogenic
Acute Animal Studies	BCS product provided angiographic occlusion immediately following treatment	

Basis for Determination of Substantial Equivalence:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Barricade Embolization Coil System is determined by Blockade Medical, to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2013

Blockade Medical
Ms. Rebecca K Pine
Regulatory Affairs
18 Technology Dr. Suite 169
Irvine, CA 92618

Re: K123338
Trade/Device Name: Barricade Embolization Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG
Dated: February 8, 2013
Received: February 11, 2013

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5. **Indications for Use Statement**

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123338

Device Name: **Barricade Embolization Coil System**

Indications for Use:

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AND/OR

Prescription Use X
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.03.28 12:07:28 -04'00'

(Division Sign-Off)
Division of Neurological and
Physical Medicine Devices

510(k) Number K123338